## REMARKS

*Status of Claims*

Claims 1 – 26 were original in the application. Claims 1 – 13 and 23 – 25 have been withdrawn. Claim 14 has been currently amended. Claims 14 – 22 and 26 are submitted for examination on the merits.

Objection to the Drawings

A responsive amendment to the drawings has been proffered.

*Rejection Pursuant to 35 USC 112*

The specification has been responsively amended.

*Rejection Pursuant to 35 USC 103*

Claims 14 - 22 and 26 were rejected as being obvious over Wulfman et al. U.S. Patent No. 2002/0007190.

The Examiner cited Wulfman as disclosing the invention substantially as claimed including a method of oscillating a high speed surgical burr (par. 130-135) including providing a motive source (ref. 16, Fig. 1), connecting the motive source via a drive shaft assembly to a burr (ref. 25, Fig. 3), oscillating the burr at a rate to cut or abrade bone (par. 75; Wulfman et al. disclose that a variety of motors can be used to achieve the desired oscillatory rates such as those specified in the claims of the application), oscillating the burr over a portion of a full circle (par. 75; the drive shaft

assembly can be configured to either create bidirectional movement of the burr with clockwise and counterclockwise movement or movement over an entire circle), providing a burr that is unshielded when used in an operation (see Fig. 13A-13C), cooling and clearing the burr by fluid irrigation and fluid and removing debris by suction (par. 96 and 103), coupling the drive shaft assembly to the burr by a resiliently biased slip clutch (see Fig. 3), and having a overlapping portion of a drive shaft and driven shaft that are telescopically over each other (see Fig. 3).

Paragraph [0075] of Wulfman upon which the step of oscillating the burr at a oscillatory rate effective for cutting or abrading bone over a portion of a full circle so that the burr cuts or abrades bone or hard matter, while leaving softer tissues substantially or entirely undamaged, states:

> [0075] According to preferred embodiments of the material removal system of the present invention, the drive system may be unidirectional and capable of rotating drive shaft 25 in one rotational direction, or **it may be selectively bi-directional and capable of rotating drive shaft 25 selectively in both a clockwise and counterclockwise direction**. Drive system 24 is also preferably capable of rotating drive shaft 25 at variable speeds ranging from 500 rpm to 200,000 rpm, more preferably from 500 to 150,000 rpm. In an exemplary embodiment of the invention, drive system 24 is a direct current variable speed micro-motor capable of operating at rotational speeds of from 500 rpm to 150,000 rpm. It is understood that a variety of motors may be employed in the system and the range of speeds and capabilities may vary according to the type and site of material removed, and the type of cutter assembly utilized. The present invention also contemplates the use of alternative means of rotating drive shaft 25, such as air-driven turbines, and the like. (emphasis added)

No where in paragraph [0075] or elsewhere that applicant can identify does Wulfman disclose oscillating a burr to any extent, let alone only a portion of a full circle. Having a drive system that can be selectively bidirectional is not an oscillating source by any

means. Almost all, if not all, automobiles have selectively bidirectional drives because they have a reverse gear. This clearly does not mean that any of them has an oscillating drive. The bidirectional drive of Wulfman is described in more detail at paragraph [0015] where it is stated:

> [0015] In one embodiment, the cutter assembly drive shaft operates bidirectionally and the adjustable diameter cutter is expanded or retracted selectively and controllably upon rotation in opposite directions. Upon rotation of the drive shaft and dual cutter assembly in a first direction, the fixed diameter cutter is used as the primary cutting head and the expandable cutter remains in a smaller diameter condition, while upon rotation of the dual cutter assembly in a second direction, opposite the first, the expandable cutter is in a larger diameter condition and serves as the primary cutter. The present invention uses hydrodynamic, centrifugal and/or frictional forces to expand and contract the dual cutter assembly, thereby obviating the need for additional actuation systems, which add considerable complexity and rigidity to such systems.

The cutter head has two cutters, one with an variable size and one with a fixed size. The variably sized cutter changes size when rotating in different directions. Whichever of the two cutters is larger acts as the primary cutter. Paragraph [0131] describes selective bidirectional rotation of the cutters in order to change cutter diameters, cut a pilot hole and then subsequently cut additional material. At all times, when any one of the two cutters is cutting, it is rotating in only one direction. Clearly, the drive of Wulfman is **not oscillating**[1], particularly at in the kHz range, since this would always make the variably sized cutter the primary cutter in every application of

[1] Merriam-Webster's International Unabridged Dictionary defines "oscillate" to mean to swing backward and forward like a pendulum or vibrate. The repetitive, periodic or cyclic motion of a pendulum is not what is described as selective bidirectionality in Wulfman, but exactly the opposite of a pendulum in that the rotation is reversible based on the random and arbitrary selection of the use according to what size bore is desired to be cut.

use, thus making both the use of "selective" bidirectionality a meaningless qualification of the drive and the use of "primary" a meaningless qualification of the cutters' roles.

The problem to be solved in Wulfman, namely boring out a smaller amount of material intraluminally and then reboring the pilot pass into a larger bore by cutting out additional material from the same bore is entirely different than and irrelevant to the problem of the claim 14 of automatically cutting hard tissue, but not softer tissue that also contacts the burr.

Moreover, Wulfman never discloses partial rotation of the cutter head in each oscillation, thereby prevention the winding of softer tissues in the oscillating burr, which results in their tearing or cutting. However, partial rotation of the cutter head in each oscillation is nevertheless effective to grind hard tissues, such as bone. The result is a burring tool which cuts or abrades bone or hard matter, while leaving softer tissues substantially or entirely undamaged. This is not a result expressly or inherently obtained in Wulfman. Nor is there any reason derivable from or which emerges in any sense from Wulfman which renders such a modification of Wulfman to realize cutting or abrading bone or hard matter, while leaving softer tissues substantially or entirely undamaged.

Although not stated, but to the extent that the Examiner might be citing Wulfman in view of common knowledge, pursuant to MPEP 2144.03 the applicant asserts that it is never appropriate to rely solely on "common knowledge" in the art without evidentiary support in the record, as the principal evidence upon which a rejection is based. *Zurko*, 258 F.3d at 1385, 59 USPQ2d at 1697. The Applicant challenges the factual assertions made with respect to claims 14 – 22 and 26 as not properly officially noticed or not

properly based upon common knowledge, and requests support with adequate evidence. The oscillation of a surgical burr through a partial rotation to cut hard tissue and not soft tissue, as being a choice of general knowledge, is identified as an error and contraindicated from bidirectional cutters, which provide indiscriminate cutting of all types of tissue regardless of the direction of rotation of the cutter. In other words, oscillating the burr at a oscillatory rate effective for cutting or abrading bone over only a portion of a full circle so that the burr cuts or abrades bone or hard matter, while leaving softer tissues substantially or entirely undamaged is more than simply selectively bidirectionally changing the sense of rotation of the burr, and consequently materially relevant evidence must be cited against the defined step in order to sustain an obviousness rejection. Citation to a reference giving a reason for the claimed step must be provided to sustain the rejection.

Applicant respectfully requests advancement of the claims to allowance.

Respectfully submitted,

Daniel L. Dawes
Registration No. 27,123
Myers Dawes Andras & Sherman LLP
19900 MacArthur Blvd., 11th Floor
Irvine, CA 92612
(949) 223-9600